

**IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA**

NANCY HOLLIS and DAVID HOLLIS	:	
	:	
v.	:	NO. 02-4605
	:	
SATARI CORPORATION, MAXXIM	:	
MEDICAL, INC., FIRST MEDICA	:	
ASSOCIATION, CRANBERRY (M) SDN-BHD,	:	
JOHNSON & JOHNSON, SAFESKIN	:	
CORPORATION, KIMBERLY-CLARK	:	IN RE LATEX GLOVES PRODUCTS
CORPORATION, ALLEGIANCE	:	LIABILITY LITIGATION
HEALTHCARE CORPORATION, BAXTER	:	NO. 1148
HEALTHCARE CORPORATION, ANSELL	:	
PERRY, ANSELL PROTECTIVE PRODUCTS,	:	
INC., SMITH & NEPHEW, INC., and	:	
BECTON, DICKINSON and COMPANY	:	

**DEFENDANT SEMPERMED USA'S ANSWER WITH
AFFIRMATIVE DEFENSES TO PLAINTIFFS' COMPLAINT**

COMES NOW, Defendant Sempermed USA, and in answer to Plaintiffs' Complaint,
does hereby aver as follows:

1. Defendant lacks sufficient information and belief to admit the allegations of
Paragraph 1 and therefore denies said allegations.

2. Defendant lacks sufficient information and belief to admit the allegations of
Paragraph 2 and therefore denies said allegations.

3. Defendant lacks sufficient information and belief to admit the allegations of
Paragraph 3 and therefore denies said allegations.

4. Defendant lacks sufficient information and belief to admit the allegations of
Paragraph 4 and therefore denies said allegations.

5.-6. Defendant admits only that it sells latex gloves and further denies the remaining allegations of Paragraphs 5-6.

7. Defendant denies the allegations advanced in Paragraph 7.

8. Defendant denies the allegations advanced in Paragraph 8.

9. Defendant denies the allegations advanced in Paragraph 9.

10. Defendant denies the allegations advanced in Paragraph 10.

11. Defendant lacks sufficient information and belief to admit the allegations of Paragraph 11 as no time frame is specified and therefore denies said allegations.

12. Defendant lacks sufficient information and belief to admit the allegations of Paragraph 12 and therefore denies said allegations.

13. Defendant denies the allegations advanced in Paragraph 13.

14. Defendant denies the allegations advanced in Paragraph 14.

15. Defendant denies the allegations advanced in Paragraph 15.

16. Defendant denies the allegations advanced in Paragraph 16.

17. Defendant denies the allegations advanced in Paragraph 17.

18. Defendant denies the allegations advanced in Paragraph 18.

19. Defendant denies the allegations advanced in Paragraph 19.

20. Defendant denies the allegations advanced in Paragraph 20.

21. Defendant denies the allegations advanced in Paragraph 21.

22. Defendant denies the allegations advanced in Paragraph 22.

23. Defendant denies the allegations advanced in Paragraph 23.

24. Defendant denies the allegations advanced in Paragraph 24.

25. Defendant denies the allegations advanced in Paragraph 25.

WHEREFORE, Defendant denies any liability to any party to this action and demands judgment in its favor, together with costs.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE: NO JURISDICTION

This Court lacks personal jurisdiction over Sempermed USA.

SECOND AFFIRMATIVE DEFENSE: STATUTE OF LIMITATIONS

Plaintiffs' claims are barred in whole or in part by the applicable statute of limitations.

THIRD AFFIRMATIVE DEFENSE: FEDERAL PRE-EMPTION

Plaintiffs' claims are barred in whole or in part by applicable federal laws and regulations, including the Federal Food, Drug and Cosmetic Act.

FOURTH AFFIRMATIVE DEFENSE: COMPARATIVE NEGLIGENCE

Plaintiffs' claims are barred in whole or in part because the plaintiff was comparatively negligent and such negligence contributed in whole or in part to plaintiff's alleged injuries.

FIFTH AFFIRMATIVE DEFENSE : NO DEFECT

Latex gloves have been classified by the FDA as a Class One medical device pursuant to 21 CFR § 880.6520. Because they are not unreasonably dangerous as a consequence of such classification, an essential element of plaintiffs' causes of action has been extinguished as a matter of federal law. In addition, the gloves marketed by Sempermed USA complied with all

applicable codes, standards and regulations established, adopted, promulgated or approved by the United States or the State of Mississippi relative to the manufacture and sale of latex gloves.

SIXTH AFFIRMATIVE DEFENSE: FAILURE TO STATE A CAUSE OF ACTION

Plaintiffs' Complaint is based upon mere conclusions, and plaintiff has failed to alleged ultimate facts sufficient to state a cause of action.

SEVENTH AFFIRMATIVE DEFENSE: U.C.C.

Plaintiffs' claims are barred in whole or in part by the terms of the applicable Uniform Commercial Code.

EIGHTH AFFIRMATIVE DEFENSE: MITIGATION OF DAMAGES

Plaintiffs failed to take reasonable steps to mitigate their damages, if any.

NINTH AFFIRMATIVE DEFENSE: THIRD PARTY NEGLIGENCE

Plaintiffs' damages, if any, were caused by the negligence of third parties over whom Sempermed USA had no discretion or control.

TENTH AFFIRMATIVE DEFENSE: SOPHISTICATED USER

Sempermed USA did not owe Plaintiff a duty to warn because Plaintiff was a sophisticated user of latex gloves.

ELEVENTH AFFIRMATIVE DEFENSE: LEARNED INTERMEDIARY

Sempermed USA distributed latex gloves to sophisticated users, learned intermediaries or both. In addition, Sempermed USA states that any duty to warn Plaintiff of any alleged risks was discharged by providing adequate warnings to her physicians, employers and hospitals. Therefore, the learned intermediary doctrine bars plaintiffs' claims.

TWELFTH AFFIRMATIVE DEFENSE: IDIOSYNCRATIC REACTION

Plaintiff incurred injuries, if any, as the result of an idiosyncratic reaction or an allergic reaction for which Sempermed USA is not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE: WAIVER AND ESTOPPEL

Plaintiff's claims are barred in whole or in part by the doctrine of waiver, estoppel or laches.

FOURTEENTH AFFIRMATIVE DEFENSE: STATE OF THE ART

The marketing of latex gloves by Sempermed USA was in conformity with the "State of the Art" existing at the time of such marketing. Sempermed USA further alleges that liability, including strict liability, may not be imposed as to properly manufactured devices distributed with information regarding the risk which the manufacturer knew of at the time of manufacture and that liability may not be imposed for untold risks not known at the time of such design, manufacture or marketing of the latex gloves.

FIFTEENTH AFFIRMATIVE DEFENSE: ALTERNATIVE DESIGN

Plaintiff cannot prevail on his claim that the latex gloves were defectively designed because plaintiff failed to allege and cannot demonstrate that a safer, feasible, alternative design existed.

SIXTEENTH AFFIRMATIVE DEFENSE: SET-OFF

Sempermed USA denies any and all responsibility for any of the acts alleged in the Complaint and denies that it is liable to plaintiff. However, if Sempermed USA is found to be liable to plaintiff, it is entitled to a set-off of all sums of money by settlement or otherwise entered into or received by or paid on behalf of plaintiff.

SEVENTEENTH AFFIRMATIVE DEFENSE: RESTATEMENT §402a, COMMENT K

If plaintiff has been injured by the latex gloves, then such products would be deemed to be "unavoidably unsafe products" as defined by Comment K, §402 of the Restatement of Torts (Second). Therefore, the latex gloves are not unreasonably dangerous, and Sempermed USA cannot be held liable to plaintiff.

EIGHTEENTH AFFIRMATIVE DEFENSE: SPOILIATION OF EVIDENCE

Plaintiffs' claims are barred in whole or in part because plaintiff failed to preserve the evidence and, as a result, Sempermed USA has been prejudiced.

NINETEENTH AFFIRMATIVE DEFENSE: MISUSE

Plaintiffs' claims are barred in whole or in part because plaintiff misused or abused the latex gloves in an unforeseeable manner.

TWENTIETH AFFIRMATIVE DEFENSE: RESERVATION OF RIGHTS

Sempermed USA intends to rely upon any other defenses that may become legally available hereafter or become apparent during discovery proceedings in this matter and Sempermed USA hereby reserves its rights to amend its answer to assert any such defenses.

TWENTY-FIRST AFFIRMATIVE DEFENSE: COLLATERAL SOURCES

Plaintiff may not recover any damages paid or payable by collateral sources.

WHEREFORE, defendant Sempermed USA demands judgment in its favor.

**KELLY, McLAUGHLIN, FOSTER
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DATED: _____